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| 09/701,229 | 08/23/2001 | Mohammed El-Sherbeini | 20193P | 8700 |

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| EXAMINER |
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PORTNER, VIRGINIA ALLEN

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| ART UNIT | PAPER NUMBER |
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1645

DATE MAILED: 09/16/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/701,229

Applicant(s)
El-Sherbeini et al

Examiner
Portner

Art Unit
1645



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 21, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above, claim(s) 8-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-14 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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DETAILED ACTION

Claims 1-14 are pending.

Claims 1-7 are under consideration.

Claims 8-14 have been withdrawn from consideration.

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-7 (Group I, claim(s) 1-7, drawn to a purified and isolated polynucleotide that encodes SEQ ID NO 2, is a complementary polynucleotide of SEQ ID NO 2, a natural mutant polynucleotides of SEQ ID NO 2 or a polynucleotides that comprises at least 25 nucleotides of any of the other embodiments of polynucleotide that encodes SEQ ID NO 2 or a mutant of SEQ ID NO 2) in Paper No. 7 is acknowledged.

The traversal is on the ground(s) that the examiner's interpretation of "the terminology "natural MurD mutant" "is far outside the commonly accepted definition of mutant".

2. This argument has not been found persuasive because the examiner found within the definition of a "natural mutant" set forth in the instant specification at page 13, lines 25-31, homologues of *Pseudomonas aeruginosa* MurD, which would include *E.coli* MurD. Additional disclosure in the instant specification at pages 4, lines 11-12; page 7, lines 34-38; page 9, lines 34-35; and page 14, line 7, defines the natural mutants of the invention to evidence "similar activity" and site directed mutations. *E.coli* MurD is encoded by a nucleotide sequence that encodes a protein of similar

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activity and comprises mutations that result in a nucleotide sequence that encodes a homologue of *Pseudomonas aeruginosa* MurD protein.

The requirement (Lack of Unity of Invention: The Instantly claimed invention lacks Unity of invention in light of the prior art disclosing a natural MurD mutant of SEQ ID NO 2, produced by *E.coli*, and has the biological enzymatic activity of MurD, specifically a UDP-MurNAc-L-Ala-D-Glu synthetase. The following lack of unity is being set forth in light of the fact that the first appearing invention directed to natural mutants of a polynucleotide that encodes a MurD polypeptide was known in the prior art, and therefore does not define a unifying special technical feature that defines over the prior (International Search Report, October 21, 1999) is still deemed proper and is therefore made FINAL.

3. Claims 8-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Groups II-V, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7, dated July 18, 2003.

Priority

4. If applicant desires priority under 35 U.S.C. 119 and 120 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether

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patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

If the application is a utility or plant application filed on or after November 29, 2000, any claim for priority must be made during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2) and (a)(5). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) a surcharge under 37 CFR 1.17(t), and (2) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Commissioner may require additional information where there is a question whether the delay was unintentional. The petition should be directed to the Office of Petitions, Box DAC, Assistant Commissioner for Patents, Washington, DC 20231.

Specification

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5. The disclosure is objected to because of the following informalities: At page 1, lines 28-29, the phrase "--a single molecule composed of peptidoglycan--" was found. What the "--" is intended to mean is unclear. Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 101

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 5-6 are directed to a polynucleotide and host cell that do not comprise a heterologous polynucleotide, nor is the claimed polynucleotide and host required to be isolated and purified, but only refer directly or indirectly to claim 1 in order to define the type of polynucleotide being claimed. The claimed invention is directed to non-statutory subject matter. This rejection could be obviated by amending claims 5-6 to recite --An isolated and purified-- and -- A host cell comprising a heterologous expression vector--.

Claim Rejections - 35 U.S.C. § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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9. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 depends from claim 1, claim 1 being a claim directed to various embodiments of the instant invention and includes mutants, and fragments of the recited SEQ ID Nos of claim 1. Claim 4 is directed to “[T]he polynucleotide of claim 1 comprising the nucleotide sequence of SEQ ID NO 1. SEQ ID NO 1 lacks antecedent basis in claim 1. It is not clear whether the claimed invention is the combination of the polynucleotide of claim 1 together with the polynucleotide of claim 4, or whether a “wherein” clause should be set forth in claim 4, or whether the phrase --further comprising-- should be recited. Clarification of what the polynucleotide of claim 4 comprises in light of the fact that SEQ ID No 1 encodes a sequence larger than the open reading frame encoded amino acid sequence of SEQ ID NO 2; as well as SEQ ID NO 1 lacks antecedent basis in claim 1, is requested.

Claim Rejections - 35 U.S.C. § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

11. Claims 1-3, 5-6(a, c and d (the 25 polynucleotides need not be 25 consecutive polynucleotides, see sequence alignment provided and is not limited to just murD of Pseudomonas aeruginosa murD gene)) are rejected under 35 U.S.C. 102(e) as being anticipated by Hoskins et al (US Pat. 5,834,270; effective filing date June 18, 1996).

Hoskins et al disclose the instantly claimed invention directed to a purified and isolated polynucleotide that encodes a polypeptide having an amino acid sequence (includes fragments of SEQ ID No. 2, based upon the definition in the instant specification) of SEQ ID No. 2 (a fragment of SEQ ID NO 2), and also represents a naturally occurring mutant of SEQ ID NO 2, wherein the encoded protein is a MurD protein, a homologue of Pseudomonas aeruginosa MurD protein. ^{The Instant Specification} At page 13, lines 25-31, defines the claimed invention to include fragments, and homologues of the SEQ ID NO 1, and which encode homologs of SEQ ID No. 2 which are MurD polypeptides (see Hoskins et al, claims 1-7, col. 22-24). Hoskins et al anticipates the instantly claimed invention.

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12. Claims 1(a-d), 2-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Rubenfield et al (US Pat.6,551,795, effective filing date February 18, 1998).

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(Instant claim 1) Rubenfield et al disclose the instantly claimed invention directed to:

a. purified and isolated polynucleotide encoding an amino acid sequence of SEQ ID NO 2 (See SEQ ID NO 7702,7552,7623, 7624; (SEQ ID NO 2 of the instant Application encodes SEQ ID NO 7702 of Rubenfield as they share 100% sequence identity based upon back translation of SEQ ID NO 2 to a polynucleotide sequence);

b. A polynucleotide complementary to the polynucleotide of (a) (see col. 10, lines 55-67; col. 6, lines 64-67);

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c. A polynucleotide representing a naturally occurring mutant of (a), SEQ ID Nos 7702-7704 varies from SEQ ID NO 1, by only a few nucleotides and is a Pseudomonas aeruginosa coding sequence; and

d. A polynucleotide that comprises at least 25 consecutive nucleotides of the polynucleotides of (a), (b) or (c) and is specific for murD of Pseudomonas aeruginosa (SEQ ID No 7702 is specific to Pseudomonas aeruginosa).

(Instant claims 2-3) wherein the polynucleotide comprises natural nucleotides (see col. 6, lines 50-51), modified and non-natural linkages between the nucleotides (see col. 10, lines 52-53, conjugates).

(Instant claim 5) expression vector (see col. 11, lines 46-54);

(Instant claim 6) host cell comprising the expression vector of claim 5 (see col. 15, lines 13-23);

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(Instant claim 7) process of expressing MurD protein of *Pseudomonas aeruginosa* comprising the steps of: transforming a suitable host cell with an expression vector (see col. 11, lines 46-54); and culturing the host cell under conditions which allow expression of the MurD protein (see col. 22, lines 23-38). Rubenfield et al anticipate the instantly claimed invention.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

14. Fleishman et al (US Pat. 6,506,581) is cited to show a purified and isolated polynucleotide that comprises at least 42 nucleotides encoded by a polynucleotide that shares an amino acid sequence with SEQ ID No. 2 (see sequence alignment).

15.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.

The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp

September 9, 2003


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